

NC 2009 H1N1 Pandemic Influenza Vaccine Distribution Plan

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Introduction

Vaccination is the primary control measure to prevent influenza. The pharmaceutical industry is actively manufacturing the 2009 H1N1 pandemic vaccine. The purpose of this chapter is to outline the key steps in the process of vaccine acquisition and delivery during an influenza pandemic.

The Advisory Committee on Immunization Practices (ACIP) has drafted vaccine priority group recommendations which are outlined in the MMWR released in August of 2009. Unlike previous pandemic vaccine plans, the ACIP recommended Target Groups for the 2009 H1N1 vaccine. Those Target Groups include:

- pregnant women;
- household contacts of infants under 6 months;
- healthcare and emergency medical services workers;
- young people between 6 months and 24 years of age;
- nonelderly adults (ages 25-64) with chronic medical conditions that confer a higher risk for influenza-related complications

According to the MMWR released 8-21-09 containing the ACIP recommendations, "Health-care personnel (HCP) include all paid and unpaid persons working in health-care settings who have the potential for exposure to patients with influenza, infectious materials, including body substances, contaminated medical supplies and equipment, or contaminated environmental surfaces. HCP might include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health-care facility, and persons (e.g., clerical, dietary, housekeeping, maintenance, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP. The recommendations in this report apply to HCP in acute-care hospitals, nursing homes, skilled nursing facilities, physicians' offices, urgent care centers, and outpatient clinics, and to persons who provide home health care and emergency medical services. Emergency medical services personnel might include persons in an occupation (e.g., emergency medical technicians and fire fighters) who provide emergency medical care as part of their normal job duties. Chronic medical conditions that confer a higher risk for influenza-related complications include chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, cognitive, neurologic/neuromuscular, hematologic, or metabolic disorders (including diabetes mellitus) or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus)."

As vaccine becomes available, it will be made available not only to the above listed Target Groups, but to any resident who wishes to receive it.

The North Carolina Division of Public Health (NC DPH) will rely on expertise from the NC Immunization Branch and the NC Strategic National Stockpile program in the NC Office of Preparedness and Response (PHP&R) to receive, allocate, distribute, and provide guidance for implementing this plan. Local Health Departments and the counties of North Carolina will implement the vaccination plan.

Assumptions

- Vaccine for 2009 H1N1 will become available in mid-October 2009.
- An “early roll out” of vaccine may occur in late September.
- As the vaccine does become available, the demand will exceed the supply for some time.
- Pandemic vaccine will be allocated to project areas in proportion to their total population. It is anticipated that, based on population for the state, North Carolina will receive 3% of the vaccine.
- The ACIP Recommended 2009 H1N1 Pandemic Influenza Vaccine Target Groups will be followed until vaccine availability matches demand and/or the evaluation of the pandemic determines that a change in the priority groups is recommended.
- All states will be in need of vaccine and a formal request process, similar to that of requesting SNS assets will not be required.
- The North Carolina State Emergency Operations Plan will be followed during the event as outlined in NCGS 166A.
- NC will continue to operate as a decentralized system and as such, all activities are overseen by the state, but are implemented in the counties.

Vaccine Request

State Request

North Carolina will follow the vaccine request procedures as presented by CDC at the time of availability and need. All states will be in need of vaccine and it will be shipped as it becomes available to the states based on the percentage of the total US population that resides within that state.

County Request

Each county or district health department will be allocated vaccine as outlined in the Apportionment section of this plan. Counties will identify the locations to which vaccine should be shipped. Vaccine will be pushed to the locations chosen by local public health. A type of pre-registration program was developed by the state and implemented by the counties. Each county contacted potential H1N1 vaccine providers, and submitted the list to the state. The state completes the process of obtaining the Provider Agreements.

Material Management

Receipt

Vaccine and the associated administration supplies will be received at locations designated by each local health department. These locations may include the health department, hospitals, private providers, pharmacies, clinics, etc.

Storage

Local health departments and all other locations receiving vaccine are obligated, by written agreement with the North Carolina Immunization Branch, to follow all vaccine storage and handling guidelines established by the Immunization Branch and the CDC. These guidelines may be found at:

<http://www.immunizenc.com/ManagVaccines.htm#storage>. In addition, vaccine should be stored in locations with controlled access so that unauthorized personnel do not have access to H1N1 vaccine.

Shipping

Vaccine will be shipped using climate controlled containers. H1N1 vaccine will be distributed through McKesson Specialty, Inc to public and private providers, similar to how UCVPD (childhood) vaccines are currently distributed. Each shipment will have a minimum of 100 doses (10 vials) of a single type of vaccine. Shipments of vaccine will continue until no additional vaccine is needed.

Chain of Custody

A chain of custody form (see Appendix A: Forms) shall be completed for any vaccine a local health department provides from its allocation to another entity. .

Vaccine Apportionment

A vaccine apportionment formula will be applied that is in compliance with the ACIP Recommended 2009 H1N1 Pandemic Influenza Vaccine Priority Groups. The apportionment is by County and based on population and target groups. It is assumed (1) that hospital workers will be vaccinated at their place of employment (2) all other pandemic vaccinations will be performed through plans developed and implemented at the Local Health Department (3) the proportion of the population in high risk groups is roughly the same throughout the state, and (4) population in all counties has increased since the last available estimates. Changes in this apportionment will be made as target groups are vaccinated, reporting reveals the need to alter the formula, priority groups are altered based on the investigation of the pandemic, etc.

Vaccine will be apportioned according to the following formula:

- 1) Hospitals: 15% - divided based on annual ED visits
- 2) Local Health Department: 35% - divided based on percentage of the NC population meeting the target groups residing in the county
- 3) Private Providers: 45% - divided based on size and type of target group served
- 4) Retail Pharmacies: 5% - divided based on the number of vaccines able to administer

Distribution

State

McKesson Specialty, Inc will handle delivery to all sites authorized by North Carolina. There is not an anticipated need for the state to transport vaccine.

PHP&R has an MOA in place with NC Emergency Management (NCEM) to provide transportation and security from the RSS to the designated location within the county should the need arise. The location in the county shall be either the health department or the local receiving site (LRS). The address of these locations is on file with PHP&R. Transportation may be provided through the NCEM private trucking contract or other available transportation including patrol cars.

Local

It is anticipated that local health departments (LHD) will need to complete distribution on a very small scale to area providers who do not meet the minimum ship to order for McKesson Specialty, Inc. In those cases, the LHD should work with the provider to ensure that cold chain is maintained through out the transfer.

Security

State

McKesson Specialty, Inc will handle delivery to all sites authorized by North Carolina. There is not an anticipated need for the state to provide security during transport of vaccine. However, security for transportation from the RSS to the LRS, if required, is provided by NC State Highway Patrol through an MOA between NCEM and PHP&R.

Local

Should a LHD require security, these arrangements are made with the local law enforcement agencies and can be supplemented through NC State Highway Patrol if the county makes such a request through NCEM. The arrangements are already in place as a result of SNS planning.

Vaccination

Vaccine will be administered to NC residents through health departments, hospitals, private providers and pharmacies. Each county health department has a Mass Dispensing/Vaccination plan that is reviewed by the state for completeness. Many models for administration can be used including holding large H1N1 vaccination clinics or extending hours of normal clinics.

Plans vary by LHD, but, approximately 30-50 volunteers would be needed to operate what will be initially small clinics. Operation of a small drive through clinic would require, at minimum, 18 non-medical staff (greeters, crowd control/security, form completion, and discharge) and 12 medical staff for vaccination. As more vaccine

becomes available and vaccine is available to the general public, larger numbers of volunteers may be needed to operate larger clinics open for longer periods of time.

Record Keeping

Records of vaccine administered may be entered in the NC Immunization Registry. For providers who do not participate in NCIR or are unable to use NCIR for another reason, a Pandemic Flu Vaccine Administration Log is attached (Appendix A: Forms). The log will be completed and returned weekly.

In addition to recording doses administered, regular reporting of wasted or expired doses will be required. The Wasted/Expired Form is found in Appendix A.

Appendix A:

Forms

North Carolina Department of Health and Human Services
Division of Public Health

Pandemic Influenza Vaccine Chain of Custody Form

Originating From:

Organization _____

Street Address _____

City _____ Phone number: _____

Delivered To:

Organization _____

Street Address _____

City _____ Phone number: _____

Contents of shipment:

Vaccine Type _____

Manufacturer/Lot# _____

Expiration date _____

vials/size vials _____

Vaccine Type _____

Manufacturer/Lot# _____

Expiration date _____

vials/size vials _____

Vaccine Type _____

Manufacturer/Lot# _____

Expiration date _____

vials/size vials _____

Vaccine Type _____

Manufacturer/Lot# _____

Expiration date _____

#vials/size vials _____

Total number of vials: _____

Temperature, quantity and condition of shipment should be checked on receipt prior to accepting custody of the vaccine.

Packed by/Date

Delivered by/Date

Received by/Date

Date Reporting _____

[illegible]

Purpose: To provide a generic method for immunization providers to report wasted/expired vaccine to the North Carolina Immunization Branch.

Preparation:

1. Complete the form following the example. Include provider name and federal ID number.
2. Return all open and unopened vials and manufacturer's pre-filled syringes of spoiled or expired vaccine.
3. **Do not return drawn vaccine.** Dispose of the vaccine at your facility. Document on this form the vaccine was wasted and disposed of at your facility.
4. Place wasted/expired vaccine (even opened partial vials) in a plastic bag with the completed form.
5. Make a copy for your records.

Distribution: Send the wasted/expired vaccine **and** form to:

Immunization Branch Materials Area
2226 Capital Blvd STE A
Raleigh, NC 27604-1478

Disposition: Retain a copy of the completed form for one year or destroy when agency need ends.

Reordering: User may copy form as needed or call 1-800-344-0569 or fax 1-800-544-3058 for more copies.

If you have vaccine you can not use before its expiration date, call us at least four (4) months prior to the expiration date. **Do not return viable vaccine.**
Call 1-800-344-0569 if you have any questions.

WEEKLY H1N1 Influenza VACCINE USE

Note: Failing to submit this form every Monday will result in suspension of your H1N1 vaccine shipments.

Reporting Period: FROM ____/____/2009 TO ____/____/2009

ORGANIZATION: _____ CONTACT PERSON: _____
 PHONE #: _____ FAX #: _____ E-MAIL ADDRESS: _____

Please enter the TOTAL number of vaccine doses administered, by age category and dose #, in the boxes below:

H1N1

Age Category	Dose 1	Dose 2
6 – 23 months		
24 – 59 months		
5 – 18 years		
25 – 49 years		
50 – 64 years		
65+ years		

H1N1 – Live Attenuated Influenza Vaccine (LAIV)

Age Category	Dose 1	Dose 2
6 – 23 months		
24 – 59 months		
5 – 18 years		
25 – 49 years		
50 – 64 years		
65+ years		

FAX or EMAIL completed forms to the IMMUNIZATION BRANCH at 1-800-544-3058 or H1N1doses@dhhs.nc.gov by 12PM (noon) EVERY MONDAY. Please do not include a cover sheet.